4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 526, 528, and 558

[Docket No. FDA-2022-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July, August, and September 2022. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve the accuracy and readability of the regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July, August, and September 2022, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental

review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book.

FDA has verified the website addresses as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During July, August, and September 2022 Requiring Evidence of Safety and/or Effectiveness

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR Section
July 18, 2022	141-043	Zoetis Inc, 333 Portage St., Kalamazoo, MI 49007	SYNOVEX Choice and SYNOVEX Plus (trenbolone acetate and estradiol benzoate implants) Implants	Supplemental approval of a reimplantation program for growing beef steers and heifers fed in confinement for slaughter for increased rate of weight gain for up to 200 days	FOI Summary, EA, FONSI	522.2478
July 18, 2022	141-348	Zoetis Inc, 333 Portage St., Kalamazoo, MI 49007	SYNOVEX ONE Feedlot (trenbolone acetate and estradiol benzoate extended-release implants) Implants	Supplemental approval of a reimplantation program for growing beef steers and heifers fed in confinement for slaughter for increased rate of weight gain for up to 200 days	FOI Summary, EA, FONSI	522.2478
July 19, 2022	200-724	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	Lubabegron, monensin, and tylosin Type C medicated feeds	Original approval for use of EXPERIOR (lubabegron Type A medicated article) with MONOVET (monensin Type A medicated article) and TYLOVET (tylosin phosphate Type A medicated article) in the manufacture of Type C medicated cattle feeds as a generic copy of NADA 141-512	FOI Summary	558.625
July 19, 2022	200-725	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	Lubabegron and monensin Type C medicated feeds	Original approval for use of EXPERIOR (lubabegron Type A medicated article) with MONOVET (monensin Type A medicated article) in the manufacture of Type C medicated cattle feeds as a generic copy of NADA 141-514	FOI Summary	558.330
July 28, 2022	141-564	Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405	Chlortetracycline and monensin Type C medicated feeds	Original approval for use of PENNCHLOR (chlortetracycline Type A medicated article) and RUMENSIN (monensin Type A medicated article) in the manufacture of Type C medicated cattle feeds	FOI Summary	558.128
July 29, 2022	200-726	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514	Firocoxib Tablets for Horses (firocoxib tablets)	Original approval for the control of pain and inflammation associated with osteoarthritis in horses as a generic copy of NADA 141-458	FOI Summary	520.928

July 29, 2022	200-727	Felix Pharmaceuticals Pvt. Ltd., 25-28 North Wall Quay, Dublin, 1, Ireland	Meloxicam 5 mg/mL Solution for Injection	Original approval for the control of pain and inflammation in dogs and cats as a generic copy of NADA 141-219	FOI Summary	522.1367
August 9, 2022	141-459	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	BRAVECTO (fluralaner topical solution) for Cats	Supplemental approval for the treatment and control of Asian longhorned tick infestations for 12 weeks in cats and kittens	FOI Summary	524.998
August 9, 2022	141-518	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	BRAVECTO PLUS (fluralaner and moxidectin topical solution) for Cats	Supplemental approval for the treatment and control of Asian longhorned tick infestations for 2 months in cats and kittens	FOI Summary	524.1001
August 11, 2022	141-565	Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405	Bacitracin and monensin Type C medicated feeds	Original approval of PENNITRACIN MD (bacitracin Type A medicated article) and COBAN (monensin Type A medicated article) to be used in the manufacture of Type C medicated feeds for the prevention of mortality caused by necrotic enteritis, or for increased rate of weight gain and improved feed efficiency, and as an aid in the prevention of coccidiosis in broiler chickens, laying hen replacement chickens, and layer breeder replacement chickens	FOI Summary	558.355
September 6, 2022	141-462	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666	Virginiamycin and narasin Type C medicated feeds	Original approval of STAFAC (virginiamycin Type A medicated article) and MONTEBAN (narasin Type A medicated article) to be used in the manufacture of Type C medicated feeds for the prevention of necrotic enteritis and coccidiosis in broiler chickens	FOI Summary	558.635

September 6, 2022	141-429	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666	Virginiamycin, narasin, and nicarbazin Type C medicated feeds	Original approval of STAFAC (virginiamycin Type A medicated article) and MAXIBAN (narasin and nicarbazin Type A medicated article) to be used in the manufacture of Type C medicated feeds for the prevention of necrotic enteritis and coccidiosis in broiler chickens	FOI Summary	558.635
September 9, 2022	141-553	Zoetis Inc, 333 Portage St., Kalamazoo, MI 49007	VALCOR (doramectin and levamisole injection) Injectable Solution	Original approval for the treatment and control of certain gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites in cattle; and for revising the tolerance for residues of doramectin in the target tissue, cattle liver	FOI Summary	522.772
September 28, 2022	200-719	Vetoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137	SIMPLERA (florfenicol, terbinafine, mometasone furoate) Otic Solution	Original approval for the treatment of otitis externa in dogs as a generic copy of NADA 141-440	FOI Summary	524.957
September 29, 2022	200-694	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland	SPECTOGARD (spectinomycin sulfate) Injectable Solution	Original approval for the treatment of bovine respiratory disease as a generic copy of NADA 141-077	FOI Summary	522.2121

Also, FDA is amending the animal drug regulations to reflect approval of supplemental applications, as listed in table 2, to change the marketing status of dosage form antimicrobial animal drug products from over-the-counter (OTC) to by veterinary prescription (Rx). These applications were submitted in voluntary compliance with the goals of the FDA Center for Veterinary Medicine's (CVM's) Judicious Use Initiative as identified by guidance for industry #263, "Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter," June 11, 2021 (https://www.fda.gov/media/130610/download).

Table 2.--Supplemental Applications Approved During July, August, and September 2022, to Change the Marketing Status of Antimicrobial Animal Drug Products from OTC to Rx

Approval date	File No.	Sponsor	Product name	21 CFR Section
July 7, 2022	041-629	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	SPECTOGARD (spectinomycin) Solution	520.2123c
July 7, 2022	055-072	Do.	ALBACILLIN (penicillin G procaine and novobiocin sodium) Intramammary Infusion	526.1698
July 19, 2022	041-245	Do.	ALBON (sulfadimethoxine) Injection 40%	522.2220
July 29, 2022	055-098	Do.	ALBADRY PLUS (penicillin G procaine and novobiocin sodium) Intramammary Infusion	526.1698
July 29, 2022	012-965	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140	TYLAN 50 (tylosin) Injection and TYLAN 200 (tylosin) Injection	522.2640
July 29, 2022	011-060	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	TERRAMYCIN (oxytetracycline HCl) Tablets	520.1660c
July 29, 2022	140-909	Do.	SULKA-S (sulfamethazine) Bolus	520.2260a
July 29, 2022	094-114	Do.	TERRAMYCIN 100 (oxytetracycline HCl) Injectable Solution; and LIQUAMYCIN 100 (oxytetracycline HCl) Injectable Solution	522.1662a
August 3, 2022	037-586	Do.	ERYTHROMAST 36 (erythromycin) Intramammary Infusion	526.820
August 5, 2022	065-124	Do.	Tetracycline Intramuscular Vet (tetracycline) Injection	Not codified
August 11, 2022	031-944	Do.	DYNAMXYIN (sulfomyxin) Injectable	522.2340
August 16, 2022	065-130	Do.	CRYSTALLINE PRO PENICILLIN G (penicillin G procaine) Injectable Suspension	522.1696b
August 30, 2022	099-402	Do.	OXYVET and AQUACHEL (oxytetracycline hydrochloride) Injectable Solution	522.1662a

September 22, 2022	008-763	Do.	TERRAMYCIN (oxytetracycline hydrochloride and polymyxin B sulfate) Ophthalmic Ointment	524.1662b
September 23, 2022	091-127	Do.	OXYVET Injection (oxytetracycline hydrochloride) Injectable Solution	522.1662a
September 23, 2022	048-287	Huvepharma EEOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	Oxytetracycline 50 (oxytetracycline hydrochloride) Injectable Solution	522.1662a

II. Changes of Sponsorship

The sponsors of the following approved applications have informed FDA that they have transferred ownership of, and all rights and interest in, the applications to another sponsor, as listed in table 3.

Table 3.--Changes of Sponsorship During July, August, and September 2022

File No.	Product name	Transferring sponsor	New sponsor	21 CFR Section
039-583	GRANULEX V (balsam Peru oil, castor oil, trypsin)	Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478	Cronus Pharma Specialities India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India	524.2620
141-513	ZIMETA (dipyrone) Injectable Solution	Kindred Biosciences, Inc., 1555 Bayshore Hwy., Suite 200, Burlingame, CA 94010	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom	522.728

Following these changes of sponsorship, Kindred Biosciences, Inc. is no longer the sponsor of an approved application. Accordingly, the drug labeler code for this firm will be removed from § 510.600(c) (21 CFR 510.600(c)).

III. Withdrawals of Approval

LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702 has requested that FDA withdraw approval of NADA 141-294 for a Bc6 rDNA construct in GTC 155-92 Goats because the product is no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations in 21 CFR 528.1070 are amended to reflect this action and in § 510.600(c) to reflect that LFB USA, Inc. is no longer the sponsor of an approved application.

IV. Change of Sponsor Name and Address

Akorn Animal Health, Inc., 1925 West Field Ct., Suite 300, Lake Forest, IL 60045 has informed FDA that it has changed its name and address to Akorn Operating Co. LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031. As provided in the regulatory text, § 510.600(c) is amended to reflect this change.

V. Technical Amendments

FDA is making the following amendments to improve the accuracy of the animal drug regulations:

- 21 CFR 510.600(c) is amended to revise the names and addresses of Akorn Animal Health, Inc.; Mylan Institutional, Inc.; and Mylan Institutional LLC in the list of sponsors of approved applications and to remove Kindred Biosciences, Inc.
- 21 CFR 520.154a is amended to add instructions for administration of bacitracin methylenedisalicylate soluble powder in drinking water of chickens, turkeys, and swine.
- 21 CFR 522.840 is amended to reflect revised conditions of use for estradiol sustained-release implants in beef steers and heifers.
- 21 CFR 522.1372 is amended to reflect the correct volume of mepivacaine solution for nerve blocks used in horses.
- 21 CFR 522.1702 is redesignated to list it in a correct alphabetical sequence.
- 21 CFR 558.128 is amended to reflect the correct terminology for chlortetracycline Type C free-choice cattle feeds used for control of anaplasmosis.
- 21 CFR 558.258 is amended to reflect approved conditions of use for free-choice fenbendazole protein and mineral blocks in beef cattle.
- 21 CFR 558.330 is amended to add a previously uncodified concentration of lubabegron Type A medicated article for use in the manufacture of Type C feeds for beef steers and heifers fed in confinement for slaughter.
- 21 CFR 558.366 is amended to correctly describe the target class for nicarbazin medicated chicken feeds.

- 21 CFR 558.450 is amended to revise the instructions for use of oxytetracycline medicated feeds in breeding swine.

VI. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires *Federal Register* publication of "notice[s]… effective as a regulation," of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a "rule of particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as "an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency."

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, 526, and 528

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 520, 522, 524, 526, 528,

and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In § 510.600:

a. In the table in paragraph (c)(1), revise the entry for "Akorn Animal Health, Inc.", remove the entries for "Kindred Biosciences, Inc." and "LFB USA, Inc.", and revise the entries for "Mylan Institutional, Inc." and "Mylan Institutional LLC"; and

b. In the table in paragraph (c)(2), revise the entries for "051079", "059399", and "063286" and remove the entries for "086047" and "086078".

The revisions read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Akorn Operating Co. LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031	059399
* * * * * * *	
Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478	051079
Mylan Institutional LLC, a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505	063286
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
051079	Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478
* * * * * * *	
059399	Akorn Operating Co. LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031

* * * * * * *	
063286	Mylan Institutional LLC, a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505
* * * * * * *	

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

4. In § 520.154a:

a. Redesignate paragraphs (d)(1) and (2) as paragraphs (d)(2) and (1), respectively;

b. In newly redesignated paragraphs (d)(1)(i)(B), (d)(1)(ii)(B), and (d)(2)(iii), add a sentence to the end of the paragraph; and

c. Revise paragraph (d)(3)(iii).

The additions and revision read as follows:

§ 520.154a Bacitracin methylenedisalicylate.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(B) * * * Use as the sole source of drinking water.

(ii) * * *

(B) * * * Use as the sole source of drinking water.

(2) * * *

(iii) * * * Use as the sole source of drinking water.

(3) * * *

(iii) *Limitations.* Prepare a fresh solution daily. Use as the sole source of drinking water. Treatment not to exceed 14 days. Not to be given to swine that weigh more than 250 pounds.

* * * * *

§ 520.928 [Amended]

5. In § 520.928, in paragraph (b)(2), remove "No. 000010" and in its place add "Nos. 000010 and 055246".

6. In § 520.1660c, revise the section heading and paragraph (d)(3) to read as follows:

§ 520.1660c Oxytetracycline hydrochloride tablets and boluses.

* * * * *

(d) * * *

(3) *Limitations*--(i) For No. 000010: Dosage should continue until the animal returns to normal and for 24 hours to 48 hours after symptoms have subsided. Treatment should not exceed 4 consecutive days. Do not exceed 500 milligrams per 100 pounds of body weight every 12 hours (10 milligrams per pound daily).

(ii) For No. 054771: Discontinue treatment 7 days prior to slaughter. Not for use in lactating dairy cattle. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

7. In § 520.2123c, revise paragraph (d)(3) to read as follows:

§ 520.2123c Spectinomycin solution.

* * * * *

(d) * * *

(3) *Limitations.* Do not administer to pigs over 15 lb body weight or over 4 weeks of age. Do not administer within 21 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

8. In § 520.2260a, revise paragraph (d)(2)(iii) to read as follows:

§ 520.2260a Sulfamethazine oblets and boluses.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations.* Do not administer for more than 5 consecutive days. Do not treat calves within 11 days of slaughter. Do not use in calves to be slaughtered under 1 month of age or in calves being fed an all milk diet. Do not use in female dairy cattle 20 months of age or older; such use may cause drug residues in milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

9. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.728 [Amended]

10. In 522.728, in paragraph (b), remove "086078" and in its place add "043264".

11. Add § 522.772 to read as follows:

§ 522.772 Doramectin and levamisole.

(a) *Specifications*. Each milliliter of solution contains 5 milligrams (mg) of doramectin and 150 mg levamisole hydrochloride.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.222 and 556.350 of this chapter.

(d) *Conditions of use*--(1) *Cattle*--(i) *Amount.* Inject subcutaneously in the neck as a single dose at a dosage of 0.2 mg doramectin (0.91 mg/lb) and 6 mg of levamisole hydrochloride per kg (2.72 mg/lb) of body weight.

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms (adults and fourth stage larvae): *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, T. longispicularis, Cooperia oncophora, C. pectinata, C. punctata, C. surnabada, Bunostomum phlebotomum* (adults only), *Strongyloides papillosus* (adults only), *Oesophagostomum radiatum, Trichuris spp.* (adults only)

and *Nematodirus helvetianus* (adults only); lungworms (adults and fourth stage larvae): *Dictyocaulus viviparus*; eyeworms (adults): *Thelazia* spp.; grubs (parasitic stages): *Hypoderma bovis* and *H. lineatum*; sucking lice: *Haematopinus eurysternus, Linognathus vituli,* and *Solenopotes capillatus*; mange mites: *Psoroptes bovis* and *Sarcoptes scabiei* in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age. Not for use in beef bulls intended for breeding over 1 year of age, dairy calves, and veal calves.

(iii) *Limitations.* Cattle must not be slaughtered for human consumption within 15 days following last treatment with this drug product. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows; use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

(2) [Reserved]

12. In § 522.840, revise paragraphs (d)(1) and(2) and remove paragraph (d)(3).

The revisions read as follows:

§ 522.840 Estradiol.

* * * * *

(d) * * *

(1) *Amounts and indications for use*--(i) *25.7-mg extended-release implant*. Insert one implant for increased rate of weight gain for up to 200 days in beef steer calves 2 months of age and older; for increased rate of weight gain for up to 200 days in growing beef steers and heifers on pasture (stocker, feeder, and slaughter); and for increased rate of weight gain and improved feed efficiency for up to 200 days in growing beef steers and heifers fed in confinement for slaughter.

(ii) *43.9-mg extended-release implant.* Insert one implant for increased rate of weight gain for up to 400 days in beef steer calves 2 months of age and older; for increased rate of

weight gain for up to 400 days in growing beef steers and heifers on pasture (stocker, feeder, and slaughter); and for increased rate of weight gain and improved feed efficiency for up to 400 days in growing beef steers and heifers fed in confinement for slaughter.

(2) *Limitations.* For subcutaneous ear implantation only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant within each separate production phase (beef steer calves 2 months of age and older, growing beef steers on pasture (stocker, feeder, and slaughter), growing beef steers and heifers fed in confinement for slaughter). Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended to for subsequent breeding. Use in these cattle may cause drug resides in milk and/or in calves born to these cows.

13. In § 522.1367, revise paragraph (b) to read as follows:

§ 522.1367 Meloxicam.

* * * * *

(b) *Sponsors*. See Nos. 000010, 016729, 017033, 055529, and 086101 in § 510.600(c) of this chapter.

* * * * *

§ 522.1372 [Amended]

14. In § 522.1372, in paragraph (c)(1), remove “3 to 5 mL” and in its place add “3 to 15 mL’.

§§ 522.1662a and 522.1662b [Redesignated as § 522.1662 and § 522.1663]

15. Redesignate §§ 522.1662a and 522.1662b as §§ 522.1662 and 522.1663, respectively.

16. In newly redesignated § 522.1662:

a. Revise the section heading;

b. Add headings to paragraphs (b)(3)(i) through (iii);

c. Remove paragraph (b)(3)(iv); and

d. Revise paragraphs (d), (e), (f), and (i)(1) through (3).

The revisions and additions read as follows:

§ 522.1662 Oxytetracycline.

* * * * *

(b) * * *

(3) * * *

(i) *Amount*. * * *

(ii) *Indications for use*. * * *

(iii) *Limitations*. * * *

* * * * *

(d)(1) *Specifications.* Each milliliter of solution contains 100 mg of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*--(i) *Amount.* Administer 3 to 5 mg of oxytetracycline per pound of body weight per day by intramuscular injection, not to exceed a total of 4 consecutive days. Administer 5 mg/lb of body weight per day for treatment of anaplasmosis, severe foot-rot, or severe cases of other indicated diseases, not to exceed a total of 4 consecutive days.

(ii) *Indications for use.* For treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum,* bacterial enteritis (scours) caused by *Escherichia coli,* wooden tongue caused by *Actinobacillus lignieresii,* leptospirosis caused by *Leptospira pomona,* and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp. For treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis.*

(iii) *Limitations.* This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Discontinue treatment at least 15 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter of solution contains 50 mg of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*. It is used as follows:

(i) *Amount*. Administer by intravenous or intramuscular injection at 3 to 5 mg/lb of body weight per day, not exceed a total of 4 consecutive days.

(ii*) Indications for use*. For treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.* and *Haemophilus spp.;* foot-rot and diphtheria caused by *Spherophorus necrophorus;* bacterial enteritis (scours) caused by *Escherichia coli;* wooden tongue caused by *Actinobacillus lignieresii;* leptospirosis caused by *Leptospira pomona;* wound infections and acute metritis caused by staphylococcal and streptococcal organisms; and treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis.*

(iii) *Limitations*. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Discontinue treatment at least 22 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Conditions of use in swine*. It is used in swine as follows:

(i) *Amount*. Administer by intramuscular injection at 3 to 5 mg/lb of body weight per day to swine, not to exceed a total of 4 consecutive days. Administered to sows at 3 mg/lb of body weight approximately 8 hours before farrowing or immediately after farrowing.

(ii) *Indications for use.* It is used for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli;* pneumonia caused by *Pasteurella multocida;* and leptospirosis caused by *Leptospira pomona.* Administered to sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

(iii) *Limitations*. Discontinue treatment at least 22 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) *Poultry (broilers, turkeys, and breeding chickens)*. It is used as follows:

(i) *Amount.* Administer subcutaneously to chickens and turkeys according to age as directed on labeling.

(ii) *Indications for use.* For the treatment of air sacculitis (air-sac disease, chronic respiratory disease) caused by *Mycoplasma gallisepticum* and *Escherichia coli;* fowl cholera caused by *Pasteurella multocida;* infectious sinusitis caused by *Mycoplasma gallisepticum;* and infectious synovitis caused by *Mycoplasma synoviae.*

(iii) *Limitations*. Do not administer to laying hens unless the eggs are used for hatching only. Discontinue treatment at least 5 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(f)(1) *Specifications.* Each milliliter of solution contains 100 mg of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*--(i) *Amount.* Administer 3 to 5 mg of oxytetracycline per pound of body weight per day by intramuscular injection, not to exceed a total of 4 consecutive days. Administer 5 mg/lb of body weight per day for treatment of anaplasmosis, severe foot-rot, or severe cases of other indicated diseases, not to exceed a total of 4 consecutive days.

(ii) *Indications for use.* For treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp.

and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum,* bacterial enteritis (scours) caused by *Escherichia coli,* wooden tongue caused by *Actinobacillus lignieresii,* leptospirosis caused by *Leptospira pomona,* and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp. For treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis.*

(iii) *Limitations.* This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Discontinue treatment at least 15 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

(i) * * *

(1) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves*--(i) *Amount.* Administer 3 to 5 mg/lb body weight per day by intramuscular injection not to exceed a total of 4 consecutive days.

(ii) *Indications for use.* For treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella spp.;* foot-rot and diphtheria caused by *Spherophorus necrophorus;* bacterial enteritis (scours) caused by *Escherichia coli;* wooden tongue caused by *Actinobacillus lignieresii;* wound infections and acute metritis caused by staphylococcal and streptococcal organisms susceptible to oxytetracycline.

(iii) *Limitations.* This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Discontinue treatment at least 18 days before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

17. In § 522.1696b, revise paragraphs (b)(2), (d)(1)(i), and (d)(2)(iii)(B) and add paragraph (d)(2)(iii)(C) to read as follows:

§ 522.1696b Penicillin G procaine aqueous suspension.

* * * * *

(b) * * *

(2) Nos. 055529 and 061133 for use as in paragraph (d)(2) of this section.

* * * * *

(d) * * *

(1) * * *

(i) *Amount*. 10,000 units per pound body weight daily by intramuscular injection.

* * * * *

(2) * * *

(iii) * * *

(B) For Nos. 016592 and 055529: Treatment should not exceed 4 consecutive days. A withdrawal period has not been established for this product in pre-ruminating calves. Discontinue treatment for the following number of days before slaughter: Cattle--10; sheep--9; and swine--7.

(C) For No. 054771: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.1702 [Redesignated as § 522.1698]

18. Redesignate § 522.1702 as § 522.1698.

§ 522.2121 [Amended]

19. In § 522.2121, in paragraph (b), remove “No. 054771” and in its place add “Nos. 054771 and 061133”.

20. In § 522.2220, revise paragraph (d)(4)(iii) to read as follows:

§ 522.2220 Sulfadimethoxine.

* * * * *

(d) * * *

(4) * * *

(iii) *Limitations.* Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Do not administer within 5 days of slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

21. In § 522.2340, revise paragraph (e)(4) to read as follows:

§ 522.2340 Sulfomyxin.

* * * * *

(e) * * *

(4) Not for use in laying hens; do not treat chickens within 5 days of slaughter. Do not treat turkeys within 7 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

22. Revise § 522.2478 to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Specifications.* (1) Each implant consists of:

(i) 100 milligrams (mg) trenbolone acetate and 14 mg estradiol benzoate (one implant consisting of four pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(ii) 200 mg trenbolone acetate and 28 mg estradiol benzoate (one implant consisting of eight pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(2) Each extended-release implant consists of:

(i) 150 mg trenbolone acetate and 21 mg estradiol benzoate (one implant consisting of six pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(ii) 200 mg trenbolone acetate and 28 mg estradiol benzoate (one implant consisting of eight pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.240 and 556.739 of this chapter.

(d) *Conditions of use*--(1) *Growing beef steers and heifers fed in confinement for slaughter*--(i) *Amounts and indications for use*--(A) An implant containing 100 mg trenbolone acetate and 14 mg estradiol benzoate as described in paragraph (a)(1)(i) of this section for increased rate of weight gain in growing beef steers fed in confinement for slaughter and for increased rate of weight gain and improved feed efficiency in growing beef heifers fed in confinement for slaughter. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph (a)(1)(i) of this section is the first implant and an implant as described in paragraph (a)(1)(i) or (ii) or (a)(2)(ii) of this section is administered 60 to 120 days later.

(B) An implant containing 200 mg trenbolone acetate and 28 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain and improved feed efficiency in growing beef steers fed in confinement for slaughter and for increased rate of weight gain in growing beef heifers fed in confinement for slaughter. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph (a)(1)(i) of this section is the first implant and an implant as described in paragraph (a)(1)(ii) of this section is administered 60 to 120 days later.

(C) An extended-release implant containing 150 mg trenbolone acetate and 21 mg estradiol benzoate as described in paragraph (a)(2)(i) of this section for increased rate of weight gain for up to 200 days.

(D) An extended-release implant containing 200 mg trenbolone acetate and 28 mg estradiol benzoate as described in paragraph (a)(2)(ii) of this section for increased rate of weight gain and improved feed efficiency for up to 200 days. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph (a)(1)(i) of this section is the first implant and an implant as described in paragraph (a)(2)(ii) of this section is administered 60 to 120 days later.

(ii) *Limitations*. Implant pellets subcutaneously in ear only. Other than as described on the labeling, this implant is not approved for repeated implantation (reimplantation) with any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter as safety and effectiveness have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. The extended-release implant described in paragraph (a)(2)(i) of this section, used as described in paragraph (d)(1)(i)(C) of this section, is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant.

(2) *Growing beef steers and heifers on pasture (stocker, feeder, and slaughter)*--

(i) *Amounts and indications for use*. An extended-release implant containing 150 mg trenbolone acetate and 21 mg estradiol benzoate as described in paragraph (a)(2)(i) of this section for increased rate of weight gain for up to 200 days.

(ii) *Limitations*. Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant. Safety and effectiveness

following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

23. In § 522.2640, revise paragraphs (b)(1), (e)(1)(iii), and (e)(2)(iii) to read as follows:

§ 522.2640 Tylosin.

* * * * *

(b) * * *

(1) No. 058198 for use of 50- or 200-mg/mL solutions as in paragraph (e) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 21 days of the last use of this drug product. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. This product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves. For No. 058198: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 14 days of the last use of this drug product. For No. 058198: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

24. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.957 [Amended]

25. In § 524.957, in paragraph (b), remove "No. 058198" and in its place add "Nos. 017030 and 058198".

26. In § 524.998, revise paragraph (c)(2)(ii) to read as follows:

§ 524.998 Fluralaner.

* * * * *

(c) * * *

(2) * * *

(ii) *Indications for use*. Kills adult fleas; for the treatment and prevention of flea infestations (*C. felis*) and the treatment and control of *I. scapularis* (black-legged tick) and *Haemaphysalis longicornis* (Asian longhorned tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 lb or greater; for the treatment and control of *D. variabilis* (American dog tick) infestations for 8 weeks in cats and kittens 6 months of age and older, and weighing 2.6 lb or greater.

* * * * *

27. In § 524.1001, revise paragraph (c)(2) to read as follows:

§ 524.1001 Fluralaner and moxidectin.

* * * * *

(c) * * *

(2) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of infections with intestinal roundworm (*Toxocara cati*, fourth-stage larvae, immature adults, and adults) and hookworm (*Ancylostoma tubaeforme*, fourth-stage larvae, immature adults, and adults); kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick

infestations (*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick)) for 2 months in cats and kittens 6 months of age and older and weighing 2.6 lb or greater.

* * * * *

28. In § 524.1662b, revise paragraph (c)(3) to read as follows:

§ 524.1662b Oxytetracycline and polymyxin B ophthalmic ointment.

* * * * *

(c) * * *

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.2620 [Amended]

29. In § 524.2620, in paragraph (b)(1), remove "051079" and in its place add "069043".

PART 526--INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

30. The authority citation for part 526 continues to read as follows:

Authority: 21 U.S.C. 360b.

31. In § 526.820, revise paragraphs (d)(3) and (e)(3) to read as follows:

§ 526.820 Erythromycin.

* * * * *

(d) * * *

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours (3 milkings) after the latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) * * *

(3) *Limitations.* For use in dry cows only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

32. In § 526.1698, revise paragraphs (d)(3) and (e)(3) to read as follows:

§ 526.1698 Penicillin G procaine and novobiocin.

* * * * *

(d) * * *

(3) *Limitations.* For udder instillation in lactating cows only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) * * *

(3) *Limitations.* For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 528--INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS

33. The authority citation for part 528 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 528.1070 [Removed]

34. Remove § 528.1070.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

35. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

36. In § 558.128:

a. Redesignate paragraphs (e)(4)(x) through (xlvii) as paragraphs (e)(4)(xxi) through (lviii);

b. Redesignate paragraphs (e)(4)(vii) through (ix) as paragraphs (e)(4)(xv) through (xvii);

c. Redesignate paragraphs (e)(4)(iii) through (vi) as paragraphs (e)(4)(v) through (viii);

d. Revise newly redesignated paragraph (e)(4)(xv); and

e. Add new paragraphs (e)(4)(iii) and (iv), (ix) through (xiv), and (xviii) through (xx).

The revision and additions read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
		* * * * * * *		
(iii) 7 to 17.5 g/ton	Monensin, 5 to 40	Growing beef steers and heifers fed in confinement for slaughter over 400 lb: For reduction of the incidence of liver abscesses and for improved feed efficiency	Feed as the sole ration to provide 70 mg chlortetracycline per head per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(iv) 7 to 17.5 g/ton	Monensin, 10 to 40	Growing beef steers and heifers fed in confinement for slaughter over 400 lb: For reduction of the incidence of liver abscesses and for prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*	Feed as the sole ration to provide 70 mg chlortetracycline per head per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin	069254

			medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	
		* * * * * * *		
(ix) 33.33 to 66.67 g/ton	Monensin, 5 to 40	Growing beef steers and heifers fed in confinement for slaughter over 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for improved feed efficiency	Feed as the sole ration to provide 0.5 mg chlortetracycline per lb. body weight per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(x) 33.33 to 66.67 g/ton	Monensin, 10 to 40	Growing beef steers and heifers fed in confinement for slaughter over 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for the prevention and control of	Feed as the sole ration to provide 0.5 mg chlortetracycline per lb. body weight per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines	069254

		coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*	access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	
(xi) 50 to 117 g/ton	Monensin, 7.14 to 40	Growing beef steers and heifers fed in confinement for slaughter under 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for improved feed efficiency	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(xii) 50 to 117 g/ton	Monensin, 10 to 40	Growing beef steers and heifers fed in confinement for slaughter under 700 lb: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for the	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow	069254

		prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*	horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	
(xiii) 50 to 117 g/ton	Monensin, 7.14 to 40	Growing beef steers and heifers fed in confinement for slaughter: For the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline and for improved feed efficiency	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(xiv) 50 to 117 g/ton	Monensin, 10 to 40	Growing beef steers and heifers fed in confinement for slaughter: For the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in	069254

		chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*	liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	
(xv) to provide 0.5 to 2.0 mg/lb of body weight daily		Beef cattle and nonlactating dairy cattle: As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline	In Type C free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(4) of this section.	054771 069254
		* * * * * * *		
(xviii) 400 to 2,000 g/ton	Monensin, 5 to 40	Growing beef steers and heifers fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; for improved feed efficiency	Feed as the sole ration to provide 10 mg chlortetracycline per lb. body weight per day. Treat for not more than 5 days, then continue feeding monensin Type C medicated feed alone. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves	069254

			to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	
(xix) 400 to 2,000 g/ton	Monensin, 5 to 40	Growing beef steers and heifers: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*	Feed as the sole ration to provide 10 mg chlortetracycline per lb. body weight per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of the coccidiosis challenge, up to 480 mg monensin per head per day. Treat for not more than 5 days, then continue feeding monensin Type C medicated feed alone. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254
(xx) 400 to 2,000 g/ton	Monensin, 10 to 200	Beef calves 2 months of age and older: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*	Feed as the sole ration to provide 10 mg chlortetracycline per lb. body weight per day and 0.14 to 1.00 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 200 mg of monensin per head per day. Feed for not more than 5 days, then continue to feed monensin Type C medicated feed alone. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed	069254

			should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Monensin as provided by No. 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	

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37. In § 558.258, add paragraphs (e)(3)(iv)(A)(*3*) and (*4*) to read as follows:

§ 558.258 Fenbendazole.

(e) * * *

(3) * * *

(iv) * * *

(A) * * *

Fenbendazole concentration	Indications for use	Limitations	Sponsor
	* * * * * * *		
(*3*) 750 mg/lb of protein block (to provide 5 mg/kg body weight (2.27 mg/lb))	Beef cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*)	Feed free choice at a rate of 0.1 pound of block per 100 pounds of body weight per day for 3 days to deliver a total of 2.27 mg fenbendazole per pound of body weight. Cattle must not be slaughtered for human consumption within 16 days following last treatment with this drug product. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	000061
(*4*) 750 mg/lb of molasses block (to provide 5 mg/kg body weight (2.27 mg/lb))	Beef cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal	Feed free choice at a rate of 0.1 pound of block per 100 pounds of body weight per day for 3 days to deliver a total of 2.27 mg fenbendazole per pound of body weight. Cattle must not be slaughtered for human consumption within 11 days following last treatment with this drug product. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these	000061

	worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*)	cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

* * * * *

38. In § 558.330, revise paragraphs (a) and (d)(1)(ii) and (iii) to read as follows:

§ 558.330 Lubabegron.

(a) *Specifications*. Each pound of Type A medicated article contains 4.54 grams (10 grams per kilogram) or 22.7 grams (50 grams per kilogram) of lubabegron as lubabegron fumarate.

* * * * *

(d) * * *

(1) * * *

Lubabegron fumarate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
		* * * * * * *		
(ii) 1.25 to 4.54	Monensin, 5 to 40	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight and for improved feed efficiency during the last 14 to 91 days on feed.	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day and 50 to 480 mg monensin/head/day during the last 14 to 91 days on feed. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day). A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be	016592 058198

			fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	
(iii) 1.25 to 4.54	Monensin, 10 to 40	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 14 to 91 days on feed.	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day and 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of coccidiosis challenge, during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	016592 058198

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39. In § 558.355, redesignate paragraphs (f)(1)(iv), (v), and (vi) through (x) as paragraphs (f)(1)(vi), (vii), and (x) through (xiv), respectively, and add new paragraphs (f)(1)(iv), (v), (viii), and (ix) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(1) * * *

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * * * *				
(iv) 90 to 110	Bacitracin methylenedisalicylate, 4 to 50	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency	Feed as the sole ration throughout the feeding period. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. In the absence of coccidiosis in broiler chickens, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Not for broiler breeder replacement chickens. Monensin provided by No. 058198, bacitracin methylenedisalicylate provided by No. 069254 in §510.600(c) of this chapter.	069254
(v) 90 to 110	Bacitracin methylenedisalicylate, 4 to 50	Laying hen replacement chickens and layer breeder replacement chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*, and for increased rate of weight gain and improved feed efficiency	Feed as the sole ration throughout the feeding period. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Not for broiler breeder replacement chickens. Monensin provided by No. 058198, bacitracin methylenedisalicylate provided by No. 069254 in §510.600(c) of this chapter.	069254
* * * * * * *				
(viii) 90 to 110	Bacitracin methylenedisalicylate, 50	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix,*	Feed as the sole ration for 28 to 35 days, starting from the time chicks are placed for brooding. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of	069254

		E. tenella, *E. acervulina,* *E. brunetti, E. mivati,* and *E. maxima*, and for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*	age. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. In the absence of coccidiosis in broiler chickens, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Not for broiler breeder replacement chickens. Monensin provided by No. 058198, bacitracin methylenedisalicylate provided by No. 069254 in §510.600(c) of this chapter.	
(ix) 90 to 110	Bacitracin methylenedisalicylate, 50	Laying hen replacement chickens and layer breeder replacement chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix,* *E. tenella,* *E. acervulina,* *E. brunetti, E. mivati,* and *E. maxima*, and for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*	Feed as the sole ration for 28 to 35 days, starting from the time chicks are placed for brooding. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Not for broiler breeder replacement chickens. Monensin provided by No. 058198, bacitracin methylenedisalicylate provided by No. 069254 in §510.600(c) of this chapter.	069254

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40. In § 558.364, add paragraph (d)(2)(ii) to read as follows:

§ 558.364 Naracin and nicarbazin.

* * * * *

(d) * * *

(2) * * *

(ii) Virginiamycin as in § 558.635.

41. In § 558.366, revise paragraph (d)(1)(i) and add paragraph (d)(2) to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(d) * * *

(1) * * *

Nicarbazin in grams per ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 90.8 to 181.6		Chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton.	066104
* * * * * * *				

(2) Nicarbazin single-ingredient Type A medicated articles may also be used in combination with:

(i) [Reserved]

(ii) Virginiamycin as in § 558.635.

42. In § 558.450:

a. Revise paragraph (e)(3)(i);

b. Redesignate paragraph (e)(3)(ii) as paragraph (e)(3)(iii); and

c. Add new paragraph (e)(3)(ii).

The revision and addition read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(e) * * *

(3) * * *

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 10 mg/lb of body weight daily		Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia	Feed continuously for 7 to 14 days.	066104 069254

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
		caused by *Pasteurella multocida* susceptible to oxytetracycline		
(ii) 10 mg/lb of body weight daily		Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline	Feed continuously for not more than 14 days.	066104 069254

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43. In § 558.625, revise paragraphs (e)(2)(vii) and (viii) to read as follows:

§ 558.625 Tylosin.

* * * * *

(e) * * *

(2) * * *

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
* * * * * * *				
(vii) 8 to 10	Monensin, 5 to 40 plus lubabegron fumarate, 1.25 to 4.54	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight; for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes,* and for improved feed efficiency during the last 14 to 91 days on feed	Feed continuously as sole ration to provide 13 to 90 mg lubabegron/head/day, 50 to 480 mg monensin/head/day, and 60 to 90 mg tylosin/head/day during the last 14 to 91 days on feed. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day). A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If	016592 058198

			feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	
(viii) 8 to 10	Monensin, 10 to 40 plus lubabegron fumarate, 1.25 to 4.54	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight, for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes,* and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 14 to 91 days on feed.	Feed continuously as sole ration to provide 13 to 90 mg lubabegron/head/day, 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of coccidiosis challenge, up to 480 mg/head/day, and 60 to 90 mg tylosin/head/day during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	016592 058198

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44. In § 558.635, redesignate paragraphs (e)(1)(vii) through (ix) as paragraphs (e)(1)(ix) through (xi), respectively, and add new paragraphs (e)(1)(vii) and (viii) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(e) * * *

(1) * * *

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
		* * * * * * *		
(vii) 20	Narasin, 54 to 90	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin and for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*	Feed as the sole ration for broiler chickens. Do not feed to chickens producing eggs for human consumption. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Naracin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(viii) 20	Narasin, 27 to 54 plus nicarbazin, 27 to 54	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin and for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*	Feed as the sole ration for broiler chickens. Do not feed to chickens producing eggs for human consumption. Nicarbazin medicated broilers may show reduced heat tolerance if exposed to high temperature and high humidity. Provide adequate drinking water and ventilation during these periods. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Naracin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
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Dated: February 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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